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STUDY PROTOCOL

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Does neurocognitive training have the potential to improve dietary self-care in type 2 diabetes? Study protocol of a double-blind randomised controlled trial

Victoria Whitelock¹, Arie Nouwen^{1*}, Katrijn Houben², Olga van den Akker¹, Iraida Neira Miller³, Parth Narendan⁴, Miranda Rosenthal⁵ and Suzanne Higgs³

Abstract

Background: Dietary self-care is a key element of self-management in type 2 diabetes. It is also the most difficult aspect of diabetes self-management. Adhering to long-term dietary goals and resisting immediate food desires requires top-down inhibitory control over subcortical impulsive and emotional responses to food. Practising simple neurocognitive tasks can improve inhibitory control and health behaviours that depend on inhibitory control, such as resisting alcohol consumption. It is yet to be investigated, however, whether neurocognitive training can improve dietary self-care in people with type 2 diabetes. The aim of this randomised controlled trial is to investigate whether web-based neurocognitive training can improve the ability of people with type 2 diabetes to resist tempting foods and better adhere to a healthy dietary regime.

Methods/design: In a double-blind multicentre parallel-group randomised controlled trial, 48 patients (based on power analysis results) with type 2 diabetes recruited from secondary health care services in Birmingham and London, will be randomly allocated to either 25 online sessions of active or control working memory training. Selection criteria include being overweight/obese, having poor diabetes control and reporting to have difficulty following a healthy diet, but having good general health otherwise. Before, immediately after and 3 months after the training, assessment sessions will be conducted. Primary outcome measures include changes in working memory capacity, lab-based food intake and a 24-h guided food recall. Secondary outcome measures include changes in glycaemic control (HbA1c) and lipids. Participants' experiences of the training will be assessed qualitatively with semi-structured interviews post-training.

Discussion: This is the first trial investigating whether working memory training can improve dietary self-care in people with type 2 diabetes. If effective, this could prove to be a low-cost, easy to do online training that can be used long-term without side effects.

Trial registration: Current Controlled Trials ISRCTN22806944

Keywords: Type 2 diabetes, Working memory, Inhibitory control, Dietary self-care, Food

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Background

Dietary self-care is a key element of self-management in people with type 2 diabetes. To reduce the risk of developing both short- and long-term physical complications, patients are encouraged to reduce their energy intake and to adopt a well-balanced diet that is low in fat and sugar and high in fibre. However, many have difficulty following this advice [1]. Moreover, those who do adhere to their dietary recommendations often report feeling deprived and experiencing cravings for foods [2, 3]. The difficulties with following this diet and the burden reported by many patients together with treatment dissatisfaction have a direct effect on patient's self-reported quality of life [4, 5]. The modern food environment makes adherence to this diet especially difficult, with increases in availability, accessibility and convenience of high energy-dense food [6]. Advertising for such foods is also omnipresent and highly persuasive [7]. This presents a major challenge for anyone attempting to maintain a healthy diet, as exposure to food cues can lead to both cravings and overconsumption of these foods [8, 9]. In order to maintain a healthy diet, it is therefore essential to resist immediate temptation and focus on more distal goals. While dietary changes can be effective in improving glycaemic control [10], dietary self-care is generally poorly performed [11], and simple advice- and motivation-based interventions have had limited effects in improving this [12]. Novel and effective strategies to help people with type 2 diabetes that adhere to dietary recommendations are therefore needed.

Being able to resist tempting food requires adhering to long-term health goals and not giving in to short-term immediate desires. Dual-process theories of behaviour posit that the ability to do this depends on the balance between two different cognitive systems that control behaviour [13]: the reflective system, which promotes controlled, reflective behaviour and the impulsive system which promotes impulsive, automatic behaviour. The reflective system can exert inhibitory control over the impulsive system and is able to suppress its effects on behaviour (although not fully). When this occurs, self-control and resisting tempting foods is more likely to follow. Inhibitory control is therefore an important executive function implicated in the control of eating behaviour. Indeed, inhibitory control has been related to overeating and obesity. People with high impulsivity/weak inhibitory control are more likely to overeat [14, 15] and be overweight/obese [16, 17]. Other work has specifically demonstrated that when inhibitory control is low, eating behaviour is more strongly guided by impulsivity [18–20]. Suppression of automatic, motivational, impulsive responses to food however improves the ability to resist consumption of desirable food items [15, 21].

Neuroimaging evidence has found that people with type 2 diabetes (compared to body weight matched healthy controls) show greater neural activity in subcortical areas of the brain in response to food cues [22]. These subcortical areas are part of the brain's impulsive system [23]. There was also greater activity in response to food pictures in cortical areas including the orbito-frontal cortex and insula [22]. These regions are part of the reflective system and as such are important for inhibitory control and restraining immediate desires in favour of long-term outcomes [23]. This neuroimaging study further showed that increased activity in cortical areas was associated with better self-reported dietary self-care, whereas activity in subcortical areas was associated with poorer dietary self-care [22]. These findings suggest that interventions aimed at maximising inhibitory control may improve dietary self-care in type 2 diabetes.

Working memory capacity is an important executive control ability that has been shown to moderate the role of impulsive processes in predicting health behaviours. In people with low working memory capacity (compared to those with high working memory capacity), impulsive processes are better predictors of alcohol consumption [24, 25], cigarette use [25] and unhealthy food consumption [26, 27]. Diabetes is associated with a range of cognitive impairments [28], and deficits in executive functioning in particular (including working memory) could be contributing to difficulties in controlling food intake [29]. Evidence from studies of top-down inhibitory control demonstrate that training working memory (WM) can improve inhibitory control and change behaviour in a variety of clinical contexts, including in children with attention-deficit hyperactivity disorder [30, 31], in older people [32], problem drinkers [33] and stimulant drug abusers [34]. For example, working memory capacity increased and alcohol consumption decreased for more than 1 month afterwards in problem drinkers who underwent 25 sessions of online WM training [33]. Working memory training is believed to work by increasing activity in the prefrontal cortex, another part of the reflective system [35]. Given that common mechanisms are known to underlie responses to palatable foods and addictive substances like alcohol [36], these data suggest that cognitive training could be effective in strengthening the ability to resist tempting foods and hence improve dietary control in people with type 2 diabetes.

Aims and hypotheses

The aim of this study therefore is to investigate whether 25 sessions of neurocognitive working memory training can improve dietary self-care in people with type 2 diabetes (compared to passive control training).

Primary outcome measures

It is expected that WM training will enhance working memory capacity and reduce high-energy-dense food intake. It is important to demonstrate that the WM training effects transfer to other measures of working memory (to help rule out simple practice effects); therefore, both the trained and novel non-trained tasks will be used to assess working memory and executive functioning. Changes in food intake will be measured at a lunch buffet in the laboratory and via a 24-h food recall task to obtain a measure of usual food intake outside of the laboratory.

Secondary outcome measures

It is expected that WM training will reduce lipid and glycated haemoglobin (HbA1c) blood levels. HbA1c is considered a long-term measure of diabetes control, and hence, this will test the longer term effects of the training. Lipid blood levels will act as a biological measure of food intake; if less high-energy-dense food is consumed, lipid blood levels should be lower. Participants' experiences of the training will be assessed qualitatively with semi-structured interviews post-training.

Methods/design

Ethics

This study has been approved by the Middlesex University Ethics Committee and by an NHS Research Ethics Committee. Prior to this, the study was reviewed by the Research Committee of Diabetes UK.

Design and participants

This is a randomised, double-blind 2 (condition: active training, passive control training) \times 3 (time point: pre, post, follow-up) factorial design study. This multisite project will run in London and Birmingham, UK. Participants will be a total of 48 NHS patients with type 2 diabetes recruited from diabetes clinics at local hospitals. Patients will be informed about the research by their health care professional initially, and the researcher will be present in clinics to provide further information and answer questions. Upon acceptance to participate, the first pre-training assessment session will be arranged. Assessments will occur at baseline, immediately after and 3 months after completion of the training. Inclusion criteria are (1) have had type 2 diabetes for 2 years or more, (2) poor diabetes control (HbA1c >64 mmol/l), (3) self-reported difficulty following a healthy diet, (4) general good health, (5) overweight with a BMI ≥ 25 and (7) treatment of diabetes can include diet only, tablets or insulin (for at least the last 6 months). Exclusion criteria are (1) neurological or psychiatric disorders, including eating disorders and clinical depression, (2) recent (within the last 6 months) changes in diabetes treatment

(e.g., transfer to insulin), (3) alcohol and/or substance abuse and (4) treatment by GLP-1 or DPP-4 inhibitors. The participants will be reimbursed £10 for travel expenses for each of the three assessment sessions.

Power calculation

The power calculation for this study was based on Houben et al.'s working memory training study in problem drinkers [33]. In this study, working memory training resulted in a large effect size of 0.27 for the interaction between time and condition. We anticipate a similar large effect size in our sample. Thus, using a 2 (condition: active, passive control) \times 3 (time point: pre, post, follow-up) within-between design and assuming correlations among measures of 0.4 and a non-sphericity correction of 0.6, the estimated sample size should be at least 20 participants per group when power is set at 0.80 and $p < 0.05$. Based on previous experience with longitudinal studies, we expect an attrition rate of 15–20 %. Therefore, we will recruit a minimum of 24 participants per group to account for possible attrition (total sample size $N = 48$).

Randomisation and blinding

The participants will be randomly allocated to either the active or passive control training conditions using an online program-generated block randomisation list (blocks of ten, [37]). Condition allocation will take place during the pre-training assessment session when the participant signs up to the online training program. Both participants and the researchers conducting the assessment sessions will be blind to the training condition participants were allocated to.

Training program

The working memory training will be the same program of tasks as used by Houben et al. [33]. This was designed based on the work of Klingberg et al. [38]. The training consists of repeatedly practising three working memory tasks: letter span task, backwards digit task and visuo-spatial task. In the backwards digit task, several numbers are presented on the screen one at a time, which participants have to remember and reproduce in reverse order (using the mouse and on-screen number pad). In the visuo-spatial task, a sequence of boxes light up one at a time in a 4×4 grid. The task here is to remember the location and order in which the boxes lit up and to reproduce this using the mouse to click on the squares in the grid in the right order. In the letter span task, a sequence of letters is presented one at a time in a circle. Once the sequence has finished, one of the positions in the circle is cued and the participants have to enter the letter that appeared in this location using the keyboard. In each training session, there are 30 trials of each task.

There will be two training conditions: active and passive control training. In the active training condition, the difficulty level closely follows the working memory capacity of the participant. Following two correct answers, the number of items to remember increases by 1. Following two incorrect answers, the number of items to remember decreases by 1. In the passive control condition, the participants complete the same set of three tasks, but the difficulty level remains low so as to not train WM. The active rather than passive control group allows us to control for expectancy effects, as well as any effects that may occur due to repeated use of computers and adhering to a training schedule.

Primary outcome measures

Working memory capacity (trained tasks)

The three tasks used in the training program will also be used in an assessment version. In the assessment version, the number of items to remember for each task begins low (three items) and increases by one following two consecutive correct answers. When two incorrect answers are given, the task is terminated. The longest sequence of items correctly recalled for each of the three tasks is summed and averaged to provide a measure of WM capacity across the three WM tasks.

Working memory capacity (non-trained tasks)

These will consist of the Cambridge Neuropsychological Test Automated Battery (CANTAB, Cambridge Cognition, Cambridge, UK) Attention Switching Task, Paired Associates Learning, Spatial Span and Spatial Working Memory tasks. The Spatial Span and Spatial Working Memory tasks measure working memory ability/capacity. The Paired Associates Learning task measures visual memory and new learning. The Attention Switching Task measures interference of irrelevant information and hence top-down cognitive control processes. Outcome measures for these tasks will include reaction times, error scores, span length and memory scores.

Lab-based food intake (lunch buffet)

The participants will be provided with a staple lunch food item (egg sandwiches or cheese sandwiches) along with six different snack foods. The weight (in grams) of the snack foods has been calculated so that a similar visual amount of each food is provided. Three of the snack foods are low energy dense (carrot sticks ~110 g, ~44 kcal; plum tomatoes ~139 g, ~28 kcal; salt and vinegar rice cakes ~10.5 g, ~40 kcal) and three are high energy dense (ready salted crisps ~25 g, ~133 kcal; chocolate chip cookies ~64 g, ~323 kcal and cheese and onion rolls ~93 g, ~283 kcal). The cookies, rice cakes, cheese and onion rolls and the sandwiches will be broken up into smaller pieces to prevent the participants

from counting the number of items they eat and this influencing their intake. The food will be weighed before and after the lunch buffet (out of sight of the participant) and used to calculate how much was eaten by subtracting the post-buffet weight from the pre-buffet weight of each food.

Non-lab-based food intake (24-h guided recall)

The participants will be asked to write down everything they ate and drank on the previous day. This is a guided recall procedure which asks the participants about the time, location and eating companions of the meal [39]. While this approach covers only a limited sample of an individual's food intake, research has shown that this method provides an accurate and representative picture of usual food intake [40]. The number of low- and high-energy-dense food and drink items reported will be totalled as a measure of food/drink intake. The participants will also be asked how many junk food items and portions of fruits and vegetables they usually eat per day.

Secondary outcome measures

HbA1c and lipids

HbA1c and lipid levels will be assessed by taking blood samples which will be sent for analysis at the hospital laboratories.

Semi-structured interviews

The semi-structured interviews will take place at the end of the post-training assessment session. The purpose of this is to understand people's experiences of the training. The participants will be asked about what they had hoped to gain from the training, their experiences of it, how they managed to include it into their life and how the training affected their eating habits and the control of their diabetes.

Other measures

To characterise the study sample and to control for potential baseline differences, we will also assess a number of other measures, including BMI (height and weight will be measured without shoes and heavy outdoor clothing and used to calculate BMI kg/m²), eating style (General Food Cravings Questionnaire [41], Three Factor Eating Questionnaire-18 [42], Dutch Eating Behavior Questionnaire [43]), diabetes-related behaviours (Diabetes Specific Quality of Life Questionnaire [44], Summary of Diabetes Self-Care Activities Scale [45], Dietary Self-Efficacy Scale [46]), depressive symptoms (Patient Health Questionnaire-9 [47]), physical activity (International Physical Activity Questionnaire [48]), physiological data (blood pressure, blood glucose levels) and demographic information (gender, age, ethnicity, education level, length

of diabetes diagnosis, how the diabetes is controlled, existence of co-morbid conditions). Illness-related information will be collected at each of the three assessment sessions to track any changes in co-morbid conditions and diabetes treatment. Mood and hunger will be measured both before and after the blood tests, computer tasks and lunch buffet, as these could influence task performance [49–51]. Food-specific inhibition will be assessed using a food go/no-go task. This task consists of 200 trials split across four blocks. In blocks one and two, the participants are instructed to respond (press the space bar on the keyboard) when they see a picture of toiletries and to withhold a response when they see sports-related pictures. In blocks three and four, the participants are instructed to respond to pictures of stationary and withhold responses to food-related pictures. Fewer commission errors (responding to no-go trials) on no-go food picture trials compared to no-go sports objects trials will indicate greater baseline food-specific inhibitory control ability.

Procedure

Assessment sessions

Assessment sessions will last approximately 2.5 h. The participants will provide informed consent at the beginning of the pre-training assessment session. See Table 1 for the order of completion of the tasks. For the lunch buffet, the participants will be given 15 min to eat (alone) and will be told to eat as much or as little as they wish. Questionnaires regarding eating habits will be completed last to avoid any influence on other responses. The post-training and follow-up assessment sessions will be the same as the pre-training assessment

session, except that consent will not need to be re-taken, and in addition, the semi-structured interview will be conducted (post-training assessment) and the participants will be probed about their awareness of the purpose of the lunch buffet (follow-up assessment). See Fig. 1. for a flowchart of how the participants will progress through the trial.

Training

The training starts the day after the pre-training assessment session and is completed online in the comfort of the participants' own homes. The participants will complete 25 online training sessions over a minimum of 25 days and a maximum of 50 days. Only one session can be completed per day, and the participants have 2 days to complete each session. Up to five sessions can be missed before they are excluded from the study.

Interviews

Sixteen interviews will be conducted (lasting a maximum of 30 min each), 8 with participants from the Birmingham site and 8 from the London site. Those interviewed will be targeted to represent the range of genders, age and ethnicities taking part in the study. At the beginning of the interviews, the participants will be reminded that their responses will be kept confidential and encouraged to be as honest as possible in their answers.

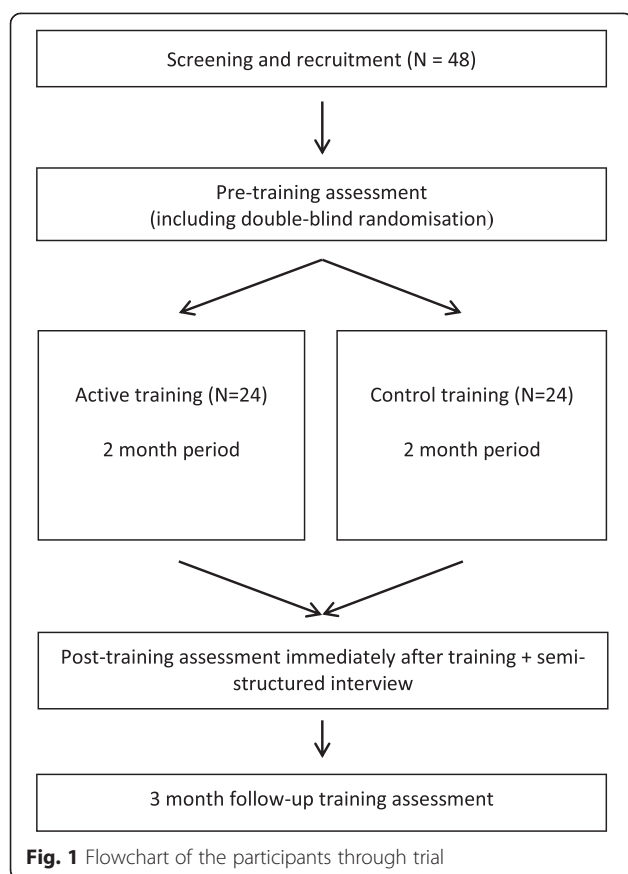
Analyses

Baseline group differences on demographic and biographic data will be assessed using ANOVAs. Any found

Table 1 Measures used at each time point and the order in which they are used

Pre-training assessment	Immediate post-training assessment	3-month follow-up assessment
Informed consent		
Hunger and mood questions	Hunger and mood questions	Hunger and mood questions
Blood pressure	Blood pressure	Blood pressure
Blood tests	Blood tests	Blood tests
Height and weight	Height and weight	Height and weight
Hunger and mood questions	Hunger and mood questions	Hunger and mood questions
Computer tasks (go/no-go, CANTAB, WM assessment and sign-up to training)	Computer tasks (go/no-go, CANTAB, WM assessment)	Computer tasks (go/no-go, CANTAB, WM assessment)
Hunger and mood questions	Hunger and mood questions	Hunger and mood questions
Buffet lunch + food liking questions	Buffet lunch + food liking questions	Buffet lunch + food liking questions
Hunger and mood questions	Hunger and mood questions	Hunger and mood questions
24-h guided recall task	24-h guided recall task	24-h guided recall task
Questionnaires (demographics, DSQOL, SDSCA, DSES, IPAQ, PHQ-9, DEBQ, TFEQ-18, GFCQ)	Questionnaires (demographics, DSQOL, SDSCA, DSES, IPAQ, PHQ-9, DEBQ, TFEQ-18, GFCQ)	Questionnaires (demographics, DSQOL, SDSCA, DSES, IPAQ, PHQ-9, DEBQ, TFEQ-18, GFCQ)
	Semi-structured interview	Awareness probe

Note: WM, working memory; DSQOL, Diabetes Specific Quality of Life Questionnaire; SDSCA, Summary of Diabetes Self-Care Activities Scale; DSES, Dietary Self-Efficacy Scale; IPAQ, International Physical Activity Questionnaire; PHQ-9, Patient Health Questionnaire-9; DEBQ, Dutch Eating Behavior Questionnaire; TFEQ-18, Three Factor Eating Questionnaire-18; GFCQ, General Food Cravings Questionnaire



to be significant will be included as co-variables on subsequent analyses. The primary and secondary outcome measures of interest will be assessed using a 2 (condition: active, control) \times 3 (time point: pre, post, follow-up) between-within ANOVA, with post hoc tests as necessary. These analyses will be done twice, once taking an Intention to Treat approach and once taking a Per-Protocol approach [52]. In an Intention to Treat approach, all participants are included in the analysis, regardless of training adherence and withdrawal. This provides a more conservative estimate of the effect of the training, compared to a Per Protocol approach to analysis which only includes the participants who completed the study.

The qualitative data obtained from the semi-structured interviews will be recorded, transcribed verbatim and imported into NVivo for analysis. A thematic analysis will be conducted to inductively identify initial codes and ultimately broader themes important to the participants' experiences of the training [53].

Discussion

This is the first trial to investigate whether working memory training can change the eating behaviour of people with type 2 diabetes. This is a highly relevant population for testing the clinical effectiveness of such

training. If successful, online working memory training could prove to be a cost-effective intervention that can be used long-term without side effects, improving the quality of life of people with type 2 diabetes. It could also prevent or delay the need for drugs or insulin to control glycaemic levels. The possible applications would also extend beyond those who have type 2 diabetes. For example, it could be used by people who are overweight/obese or have "pre-diabetes" (impaired glucose regulation) to help prevent/delay the development of type 2 diabetes.

The ideal intervention for any medical condition is one that improves the condition, is easy for patients to do and has no unpleasant short- or long-term side effects. Therefore, the secondary aim of this study is to gain an understanding of patient's experiences with the training. An online intervention is ultimately only going to be successful if patients are able to incorporate it into their life. The semi-structured interviews will allow us to assess how patients experienced the training, such as how they managed to integrate it into their lifestyle and the effects they think it had on their diet and diabetes control. This will provide future direction for research, such as investigating the effects of fewer or shorter training sessions.

As the participants will not need to attend the clinic for each training session, but rather can do it at home, we hope this will improve adherence rates. The participants can do each training session at any time and in any place suitable to them. This will allow us to assess the effectiveness of a training program that would likely be impossible if the participants had to attend the clinic for every training session. There are shortcomings to an online intervention however. Without a researcher present to ensure that the participants do each training session, patients may be more likely to not complete all sessions. Adherence to the intervention is therefore encouraged with an email reminder each day that they are now able to complete the next training session, with a URL link that the participants can click on, taking them directly to the training session. Therefore, the participants (1) receive a reminder every day to complete that day's training session and (2) do not have to remember a username and password in order to do the training. This should ensure good rates of adherence to the training program. Another limitation to online training programs is that it requires the participants to have a computer and internet access. Not all people will have this, especially older people, whom we anticipate will form a large proportion of our sample. However, according to the Office of National Statistics, 84 % of households in Great Britain have access to the internet in 2014, so we do not anticipate this being a barrier to recruitment [54].

Abbreviation

WM: working memory.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

AN, SH and KH conceptualised the study, and all authors contributed to the design of the study. VW and INM conducted data collection, along with PN and MR. VW drafted the manuscript with input from all authors. All authors have read and approved the final manuscript.

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